IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 3 CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DENISE ELSER, MD

PRELIMINARY STATEMENT

Plaintiffs seek to exclude Dr. Elser's testimony in three primary areas: 1). Dr. Elser should be precluded from offering any opinion regarding the sufficiency of Defendants' warnings; 2). Dr. Elser should be precluded from giving design opinions; and 3). Dr. Elser should be precluded from offering statements about her personal experience regarding the safety and efficacy of the pelvic mesh products as it relates to rates seen in her personal practice. This court has previously ruled that: 1). Dr. Elser does not possess the additional expertise [required] to offer testimony about what information should or should not be included in an IFU, 2). Dr. Elser has not expressed any opinions about the process of designing a product, and 3). Dr. Elser may not offer precise statistics based on her own assurances that those statistics are reliable. *In re Ethicon Inc., Pelvic Repair Sys, Prod. Liab. Litig.*, No 2327, 2016 WL 4542054 at 3-4 (S.D. W. Va. Aug. 30, 2016). Defendants appear to acquiesce in the court's prior judgements as to points 2, and 3, and concede that Dr. Elser will not offer any opinions about the adequacy of the design of the pelvic mesh products, and will not testify as to her practice's efficacy and

complication rates. (Def. Response at 6-7). Therefore, Plaintiffs will not address those topics in their reply and request that the Court adopt its prior rulings with regard to those two topics. However, while the defendants now concede that Dr. Elser does not intend to offer testimony as to the risks "that must be (and those that need not be)" in the IFU, they now seek to re-frame those same opinions, and instead have Dr. Elser opine that "Ethicon's IFU adequately describes the risks unique to any mesh surgery and that the risks Plaintiffs' experts contend are not covered in the IFU are commonly known to pelvic surgeons." Def. Resp. at 2.

Allowing Dr. Elser to offer these opinions as stated in the Defendants' response must fail for the same reasons the court already has already denied her previously stated warnings opinions. First, the defendant's concession of what opinions she will not offer directly contradicts the opinions they state she will offer: by offering an opinions that: 1). the Ethicon IFU adequately describes the risks unique to any mesh surgery and that 2). pelvic surgeons would have knowledge of risks not disclosed in the IFU, Dr. Elser is opining that the IFU is sufficient with regard to risks, and that no new risks need to be added to the IFU. Second, offering an opinion that risks not disclosed in the IFU are commonly known to pelvic surgeons is precisely what this court has ruled Dr. Elser is unqualified to do.[1] Defense's response acknowledges that this court has previously found Dr. Elser is not qualified to offer these opinions based solely on her qualifications as a urogynecologist and has excluded those opinions. (Def. Resp. at 1).

Finally, Dr. Elser's warning opinions as re-packaged and restated in Defendants' response brief must be excluded for the same reasons they were excluded before: they still suffer

[1] This court has ruled that "Dr. Elser does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." *In re Ethicon Inc.*, 2016 WL 4542054 at 3. By permitting Dr. Elser to give the opinion that "Ethicon's IFUs adequately describe the risks unique to mesh surgery", She is simply re-framing her opinion that the IFU should not include any more risks, which is precisely what this Court has already prohibited.

from the fatal flaw that Dr. Elser did not consider or consult **any** standard whatsoever, leaving her opinion devoid of any verifiable methodology, and her opinions on what risks are known to pelvic floor surgeons are speculation not based on any reliable methodology. Moreover, general unverifiable hearsay statements and opinions that a risk would be generally known by others is unreliable, irrelevant to the question to be decided by the jury, and extremely prejudicial.

This court should adopt its prior ruling regarding Dr. Elser in its entirety, with a clarification that Dr. Elser's opinions stating: 1). the applicable IFUs adequately describe the risks unique to mesh surgery, and 2). pelvic surgeons would have knowledge of undisclosed risks, should both be excluded as they are merely the defense's attempt to re-package and backdoor into evidence Dr. Elser's already excluded and unreliable opinions about what risks the applicable IFUs should or should not include.

LEGAL ARGUMENT

A. Dr. Elser failed to apply any objective standard in offering her warning opinions, in violation of *Daubert.*

This motion should be granted because Dr. Elser's opinions on the adequacy of the Ethicon's warnings are based only on Dr. Elser's subjective opinion, with no basis in or even verification with a standard from any source. The new opposition brief still fails to identify any objective standard or methodology applied by Dr. Elser, such that one could test her opinions as to what physicians already know about the risks of pelvic mesh surgery. That gap is fatal to warning opinions, as this Court recently has held. In *Sanchez v. Boston Scientific Corp.*, 2014 WL 4851989 (S.D. W. Va. Sept. 29, 2014), this Court precluded an expert's warning opinions because the expert applied no standard at all to support his opinions, concluding: "Dr. Slack's subjective and conclusory approach is evidence that his opinion is based on mere speculation and personal belief." *Id.* at *33. The same reasoning applies to Dr. Elser, who does not even know

the purpose of the IFU. (Dr. Elser 9/16/14 Dep. Tr. 120:14-17, attached as Exhibit A). Dr. Elser knows no standards, and applied no reliable standard beyond her own subjective opinion:

> Q. All I'm saying is the opinions you're offering about the warnings are not based on any standard whatsoever as to what Ethicon was required to do because you don't know what they were required to do, right?
>
> A. No, I'm commenting on what the average pelvic surgeon needs to know.
>
> Q. Is the answer to my question yes?
>
> A. Yes.

(Ex. A, Elser Deposition, at 168:17-169:4). Such an opinion, not tied to any standard, is not permitted under *Daubert*. *Sanchez*, 2014 WL 4851989, at *33.

Dr. Elser also cherry-picks information and standards for her warning opinions, ignoring testimony from Ethicon's own physicians and pelvic floor surgeons. She disregards the testimony of key Medical Affairs personnel for Ethicon when their opinions do not match her own.

> Q. Doctor, have you reviewed or relied upon any depositions of any Ethicon company witnesses in forming your opinions in this case?
>
> A. I have read them, but I did not cite them in my report
>
> Q. Which ones have you read? Where would I get a list of all the company depositions that you've – that you've read.
>
> A. That I would have to look and see which ones I have in my file, but I was not planning to specifically cite them or rely on them. I did not rely on them for this report.
>
> Q. So, even though you've reviewed some depositions of Ethicon company witnesses, there is none that you intend to rely upon in forming your opinions in this case, is that correct?
>
> A. Yes.

(Dr. Elser 3/30/16 Dep. Tr. at 14:23-15:26, attached as Exhibit B). This unreliable cherry-picking of data fails to satisfy the scientific standard under *Daubert*. *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Practices & Products Liab. Litig.*, No. MDL214MN02502RMG, 2016 WL 1251828, at **13-14 (D.S.C. Mar. 30, 2016). Failing to adequately account for contrary evidence is not reliable or scientifically sound. *McEwen v. Baltimore Washington Med. Ctr. Inc.*, 404 Fed Appx. 789, 791-92 (4th Cir. 2010). For example, Charlotte Owens testified that the IFU needed to "clearly and unambiguously communicate" necessary warnings, and that they **"needed to list each of the adverse reactions that were known to you in Medical Affairs."** (Charlotte Owens Dep. Tr. at 262:7-13, 309:23-310:3, attached as Exhibit C) (emphasis added). Similarly, David Robinson of Medical Affairs testified that the IFU **"should accurately represent what we knew to be risks,"** and that a complication would need to be listed if it had **"a frequency or a severity that had some implication for a risk/benefit ratio."** (David Robinson Dep. Tr. at 488:11-18, 489:4-10, 492:23-493:8, attached as Exhibit D) (emphasis added). Finally, Dr. James Hart, Chief Medical Officer of the Johnson & Johnson Global Surgery Group, testified that the purpose of the IFU is to:

> **provide a COMPLETE STATEMENT of what the company knows with regard to the indications, the contraindications, the warnings, the precautions and the adverse reactions for the device.**

(Dr. James Hart 12/20/13 Dep. Tr., 800:3-8; Exhibit E) (emphasis added).

Moreover, the deposition testimony of Sean O'Bryan of regulatory affairs, confirmed that Ethicon could not withhold warnings based on an assumption that surgeons would otherwise know the risks:

> Q: When you worked on that project, it was your understanding from an FDA regulatory perspective it would not be legitimate to not include warnings of potentially significant adverse events based on a decision that the surgeons would figure that out on their own?

A: No, that's correct.

(Sean O'Bryan 5/18/12 Dep. Tr. at 107:14-21, attached as Exhibit F). This testimony completely invalidates any opinion that would allow Ethicon to fail to warn based on an unverifiable claim or assumption that physicians would know the risks without being warned. Of course, that is not a standard; rather, it is an excuse created to explain the failure to provide warnings in accordance with the applicable standards.

B. Dr. Elser should not be permitted to offer unsupported, unreliable opinions based on her unsupported assumption that users would have knowledge of risks not covered in the IFU.

Dr. Elser's opinions that users would have knowledge of risks not covered in the IFU are simply an attempt by Ethicon to backdoor into evidence Dr. Elser's opinion that Ethicon did not have to warn of certain known risks. General, unverifiable hearsay statements and opinions that a risk would be generally known are wholly irrelevant to the question to be decided by the jury and extremely prejudicial. Such an opinion would be wholly unsupported because Ethicon has never studied which complications were understood by day-to-day users of pelvic mesh devices. (Marty Weisberg Dep. Tr., 11/12/15, 91:4-12, Exhibit G).

Dr. Elser's proposed testimony is, at its essence, a mechanism for the wholesale introduction of a mass of hearsay and uncorroborated speculation that has not even been confirmed to exist. There is no study produced by Ethicon or anyone else documenting that risks were known to doctors regarding the pelvic mesh products at specific times, and Dr. Elser has identified no such study that she relies on in offering her opinions. In fact, Dr. Elser has admitted that she does not believe that the purpose of the IFU is to provide the risks and complications known to surgeons, and acknowledges that a study would need to be done to determine which risks Doctors already know about:

> Q: So, from your perspective, from your perspective in your opinion, the purpose of the IFU is not to provide the risks and complications known to Ethicon regarding the Prolift to physicians. That's your perspective and your opinion, correct?
>
> A: That's my opinion and the Instructions for Use, how do I use this in the OR. That is how it's going - - I believe will be accepted by most surgeons. And you just have me -- I want to do this study now. I'm going to survey all kinds of gynecological surgeons to see if they even know what the IFU is.

(Ex. A at 168:17-169:4). The above testimony concedes that Dr. Elser does not even understand the legal purpose of the IFU, let alone have any basis to support her opinions regarding what physicians know about the risks, and she would have to do a study to determine that information. Even if she were to conduct such a survey or study now, the results would be irrelevant and prejudicial, as they would reflect what pelvic surgeons know now, not what they knew at the time of a particular patient's surgery, which is the relevant inquiry. Ethicon had a duty to warn of all material risks and not rely on speculation as to what every "generic pelvic mesh surgeon" might know. Moreover, Ethicon's witnesses should be precluded from giving such testimony, as it would be speculative and prejudicial. The questions for the jury are whether the warnings in each specific cause were adequate, and whether the doctor and patient in each specific case knew the risks despite the lack of warnings.

In their response, Ethicon contends that for example, if a plaintiff complains of dyspareunia, Dr. Elser will testify that, although dyspareunia is not specifically mentioned, [in the IFU] it is a recognized risk to surgeons performing prolapse and stress urinary incontinence surgery. (Def. Resp. at 5). However, Dr. Elser's testimony in specific cases paints a far different picture, in which she specifically acknowledges that while dyspareunia now appears in the TVT IFU beginning with the 2015 release, it was not necessary to include in as a risk in older versions of the IFU: (in this example, the November, 2001 IFU)

> Q: Do you believe it was unnecessary to have the word "dyspareunia" in the IFU at the time of Ms. Waynick's surgery in November of 2001?
>
> A: Yes
>
> Q: But you know that both of these items [chronic pain and dyspareunia] are in the IFU currently?
>
> Y: Yes
>
> Q. Do you believe that Ethicon has put unnecessary risks in their IFU?
>
> A: Do they - - yes, I think a lot of the things in the IFU are unnecessary and most good surgeons do not rely on things listed in the IFU to show complications unless it's something truly unique to the device or something you need to learn for the first time……

(Dr. Dense Elser 03/31/16 Dep. Tr. at 41:24-42:16, attached as Exhibit H.). Here, Elser is doing exactly what Defendants claim she will not do, and what the court has explicitly forbidden: offering an opinion as to the risks an IFU should and should not exclude. It is prejudicial to the plaintiff to admit this de facto opinion that the risk does not need to be in the IFU. Moreover, the opinion should not be allowed, as it is not based on any reliable scientific data or scientific methodology, but instead on unverifiable hearsay statements and personal conviction of the witness.

Conclusion

Plaintiffs request that this court adopt its prior ruling regarding Dr. Elser in its entirety, with a clarification that Dr. Elser's opinions concluding: 1). the applicable IFUs adequately describe the risks unique to mesh surgery, and 2). undisclosed risks in the IFU are already commonly known to pelvic surgeons, are also excluded.

Dated: October 21, 2016

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on October 21, 2016, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

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